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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,573	03/22/2001	Hector F. DeLuca	1256-00721	9707

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/815,573

Applicant(s)

DELUCA ET AL.

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicant's response (remarks/arguments) filed on July 5, 2005 wherein no amendment is filed, i.e., no claims are amended, cancelled, or newly submitted. Claims 1-7 are cancelled previously.

Currently, claims 8-14 are pending in this application and under examination on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (WO 96/24258) for same reasons of record stated in the Office Action dated April 1, 2005.

Deluca et al. discloses a method of improving utilization of phosphorus as to reducing or minimizing or perhaps eliminating dietary requirements of phosphorus in animals (abstract, page 3 lines 13-15) such as cattle or cow including dairy cow (see particularly page 10 line 10) comprising feeding with the instant 1 $\alpha$ -hydroxylated vitamin D compound (see page 7-8 in particular) in the effective amounts, about 5-40  $\mu$ g/kg, within the instant claim (see page 10 line 20-22; claim 12), may be in a form of top

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dressings (see page 9 line 3). See also abstract, page 5 line 30 to page 6 line 3, page 9 line 15-17, and claims 18-20.

DeLuca et al. teaches that "low phosphorus containing animal feeds reduce the polluting effects on the environment since less phosphorus is excreted in the animal's feces which are then spread on agricultural land" (see abstract).

DeLuca et al. do not expressly disclose the method therein comprising replacing all inorganic phosphorus in a diet with the known effective amount of  $1\alpha$ -hydroxylated vitamin D of prior art. DeLuca et al. do not expressly disclose that said feed contains 0% by weight of an inorganic phosphorus supplement.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to motivated to replace all inorganic phosphorus in a diet with the known effective amount of  $1\alpha$ -hydroxylated vitamin D of prior art, and said feed containing 0% by weight of an inorganic phosphorus supplement.

One having ordinary skill in the art at the time the invention was made would have been motivated to replace all inorganic phosphorus in a diet with the known effective amount of  $1\alpha$ -hydroxylated vitamin D of prior art, and said feed containing 0% by weight of an inorganic phosphorus supplement, since the known method of improving utilization of phosphorus as to reducing or minimizing or perhaps eliminating dietary requirements of phosphorus in animals in dairy cow comprising feeding with the same effective amount of  $1\alpha$ -hydroxylated vitamin D compound, about 5-40  $\mu\text{g/kg}$ , has been disclosed by DeLuca et al.

Thus, DeLuca et al. is seen to clearly provide the motivation for the instant method by eliminating dietary requirements of phosphorus or replacing all inorganic phosphorus in a diet, by administering the same effective amount of the same vitamin D compound to the same dairy cow.

DeLuca et al. have further provided the motivation for eliminating or replacing all inorganic phosphorus in a diet for the sake of eliminating or reducing the pollution of phosphorus, by teaching that "low phosphorus containing animal feeds reduce the polluting effects on the environment since less phosphorus is excreted in the animal's feces which are then spread on agricultural land".

Thus the claimed invention as a whole is clearly prima facie obvious over the cited prior art.

### ***Response to Argument***

Applicant's arguments filed July 5, 2005 with respect to the rejection made under 35 U.S.C. 103(a) as being unpatentable over Deluca et al. (WO 96/24258) of record in the previous Office Action April 1, 2005 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant asserts that "[t]here is simply no suggestion in WO 96/24258 that one could replace all inorganic phosphorous in a diet for lactating dairy cows and still maintain high milk yields in dairy cows, especially when one considers the abnormally low phosphorous content of the dairy cow's diet."

However, note that Applicant admits that “the '258 reference refers to the possibility of minimizing or perhaps eliminating the need for supplemental quantities of P in an animal diet by the incorporation of a 1 $\alpha$ -hydroxylated vitamin D compound in the animal's diet.”

Thus, as discussed in the previous Office Action, DeLuca et al. is seen to clearly provide the motivation for the instant method by eliminating dietary requirements of phosphorus or replacing all inorganic phosphorus in a diet, by administering the same effective amount of the same vitamin D compound to the same dairy cow.

DeLuca et al. have further provided the motivation for eliminating or replacing all inorganic phosphorus in a diet for the sake of eliminating or reducing the pollution of phosphorus, by teaching that “low phosphorus containing animal feeds reduce the polluting effects on the environment since less phosphorus is excreted in the animal's feces which are then spread on agricultural land”.

Additionally, Applicant's results on testing the instant vitamin D compounds in the specification at pages 13-17 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. Note that none of tests shown at Tables 2-4 at pages 15-17 is directed to 0% P in a diet by low P, 0.47% P or 0.35% P in a diet (see also page 14 line 1-5 of the specification). Therefore, the results herein are not seen to be relevant to the claimed method herein. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

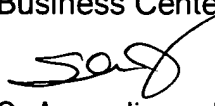
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Primary Examiner  
Art Unit 1617  
August 30, 2005